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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,429	01/22/2002	Ekambar R. Kandimalla	47508-580 (HYZ-027CIP)	7279

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,429	KANDIMALLA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-20* is/are pending in the application.

4a) Of the above claim(s) *6,7,14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8-13 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 1/22/02 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3, 5-20 are pending. Claims 6-7, and 14-15 are withdrawn.

Response to Arguments

2. Applicant's arguments filed 6-22-05 with respect to claims 18-19 have been considered but are moot in view of the new ground(s) of rejection.

3. The rejection of claims 1-3, 5, 8-13, 17, and 20 under 35 U.S.C. 103(a) as being unpatentable over Gryaznov et al. (US Patent No. 5,571,903) in view of Agrawal et al. (US Patent No. 5,691,316), is withdrawn in response to Applicant's arguments filed 6-22-05 since it is clear that Agrawal et al. does not each the terminal covalent attachment of cyclodextrin to oligonucleotides. However, a new grounds of rejection under 35 USC 103(a) is set forth below in response to Applicant's amendment of 6-22-05.

4. The rejection of claims 16-19 under 35 USC 112, 1st paragraph in response to Applicant's arguments of 6-22-05 since it is clear that the compositions of the present invention need only one enabled use to satisfy the requirements of this statute. The pharmaceutical compositions of instant claims can be used in a cell for diagnostic purposes, for example.

Double Patenting

5. Claims 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,372,427 in view of Papahadjopoulos et al. (US Patent No. 4,235,871; US-'871). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g.,

In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim(s) 18-19 of the instant application differ from the compositions recited in claims 1-22 of the issued Patent by the presence of a pharmaceutically acceptable carrier.

6. US-'871 disclose the preparation of nucleic acid liposomal formulations (col. 6, lines 31-43). The formulations of US-'871 are disclosed as having the ability to enhance the bioavailability of biologically active material, introducing genetic information into cells in vitro and in vivo, introduction of recombinant DNA segments into microbial cells, or for use in diagnostic reagents for clinical tests, see col. 3, lines 28-43.

7. It would have been obvious to the ordinary skilled artisan, at the time of the instant invention, to modify the issued claims drawn to a composition comprising cooperative oligonucleotides with a pharmaceutically acceptable carrier. One of ordinary skill in the art would have been motivated to make this modification because issued claims 11-12 are drawn to the use of the claimed compositions in an *in vitro* method for inhibiting the expression of a nucleic acid, and the prior art teaches that the presence of the carrier enhances the bioavailability of biologically active material, and aids in the delivery of nucleic acid into cells *in vitro.*

Claim Rejections - 35 USC § 103

8. Claims 1-3, 5, 8-13, 16-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gryaznov et al. (US Patent No. 5,571,903) in view of Weber et al. (1992).

9. Gryaznov et al. disclose compositions comprising a from two to five components comprising oligonucleotide moieties (of 4 to 12 monomers in length) that specifically anneal to a

target polynucleotide in a contiguous end-to-end fashion, wherein each oligonucleotide are modified to comprise a terminal binding moiety (col. 3, lines 1-30). As per col. 3, lines 10-20, it appears that the terminal binding moieties are covalently attached to the oligonucleotide by a number of different chemistries (see col. 6, lines 31-50). According to Gryaznov et al. the terminal binding moieties of the invention are brought into juxtaposition so that they from a stable covalent linkage or non-covalent complex. The terminal binding moieties of Gryaznov et al. confer an increase by at least fifty percent over the melting temperatures of the oligonucleotide moieties alone (col. 4, lines 10-15). The terminal binding pairs must also react specifically with each other (col. 6, lines 51-54). The oligonucleotides of Gryaznov et al. may also comprise encompass modified oligonucleotides that comprise internucleoside linkages that confer nuclease resistance, e.g. phosphorothioate, phosphorodithioate, phosphoramidate, or the like (see col. 5, lines 44-48).

However, Gryaznov et al. does not teach oligonucleotide moieties modified with streptavidin and biotin. Weber et al. describes the high affinity binding of streptavidin to biotin.

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Gryaznov et al. with the teachings of Weber et al. in the design of the instant invention. One of ordinary skill in the art would have been motivated to make this modification because Weber et al. clear teach the high affinity, and specificity of streptavidin binding to biotin. The binding pairs of Gryaznov et al. are disclosed as forming stable and specific complexes, and the streptavidin and biotin binding pairs are disclosed as having those characteristics (see page 3197, Introduction, of Weber et al.) It would have been obvious at the time of the instant invention to substitute one functionally equivalent binding pair

for another with the expectation that the prior art binding pair would function in the same manner as those disclosed in Gryaznov et al.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1633

JLE